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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,724	02/09/2001	Sergio A. Lira	JB01066Q	6914

24265 7590 06/17/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER
BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/780,724	Applicant(s) LIRA, SERGIO A.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* ~~MONTH(S)~~ FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2,6 and 7, drawn to a method of treating asthma comprising administering to an animal an antagonist of a mammalian CCR8 receptor wherein the antagonist is an antibody, classified in class 424, subclass 130.1.

II. Claims 1,3,6 and 7, drawn to a method of treating asthma comprising administering to an animal an antagonist of a mammalian CCR8 receptor wherein the antagonist is a small molecule, unclassifiable.

III. Claims 1,4,5,6 and 7, drawn to a method of treating asthma comprising administering to an animal an antagonist of a mammalian CCR8 receptor wherein the antagonist is a chemokine ligand, classified in class 514, subclass 2.

IV. Claims 8-11, drawn to a method of screening drugs using a CCR8 receptor polypeptide and a compound in protein binding assays wherein the compound is a peptide, classified in class 435, subclass 7.1.

V. Claims 12-15, drawn to transgenic, non-human animal whose genome lacks a functional CCR8 gene, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because the methods of each invention utilize materially distinct compounds to treat disease. The use of each distinct compound requires different individual method steps and technical considerations. Invention I uses an antibody, Invention II uses a small molecule and Invention III uses a chemokine ligand. The method steps are materially different and plurally independent from each other because each can be used

independently of the other. Furthermore, each invention is classified differently. The burden required to search Invention I, II, or III together would be undue.

Invention I and Invention IV are patentably distinct because the methods of Invention I are drawn to treating disease in vivo while the methods of Invention IV are drawn to screening drugs in vitro. The method steps are materially different and plurally independent from each other because each can be used independently of the other. The methods of Invention I are not necessary for the methods of Invention IV nor are the methods of Invention IV necessary for the methods of Invention I. Furthermore, each Invention is classified differently. The burden required to search Invention I and Invention IV together would be undue.

Inventions I-III and Invention V are patentably distinct because the methods of treating asthma can be used to treat disease while the genetically engineered animal of Invention V can be used to determine the effects of CCR8 on gene expression in vivo. The methods of Inventions I-III do not require the animal of Invention V and the animal does not require the methods. Furthermore, each Invention is classified differently. The burden required to search Inventions I, II or III and Invention V together would be undue.

Invention II and Invention IV are patentably distinct because the methods of Invention II are drawn to treating disease in vivo while the methods of Invention IV are drawn to screening drugs in vitro. The method steps are materially different and plurally independent from each other because each can be used independently of the other. The methods of Invention II are not necessary for the methods of Invention IV nor are the methods of Invention IV necessary for the methods of Invention II. Furthermore, each Invention is classified differently. The burden required to search Invention II and Invention IV together would be undue.

Invention III and Invention IV are patentably distinct because the methods of Invention III are drawn to treating disease in vivo while the methods of Invention IV are drawn to screening

drugs in vitro. The method steps are materially different and plurally independent from each other because each can be used independently of the other. The methods of Invention III are not necessary for the methods of Invention IV nor are the methods of Invention IV necessary for the methods of Invention III. Furthermore, each Invention is classified differently. The burden required to search Invention III and Invention IV together would be undue.

Inventions IV and Invention V are patentably distinct because the methods of Invention IV can be used to screen drugs while the genetically engineered animal of Invention V can be used to determine the effects of CCR8 on gene expression in vivo. The methods of Invention IV do not require the animal of Invention V and the animal does not require the methods. Furthermore, each Invention is classified differently. The burden required to search Invention IV and Invention V together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

a) an anti-inflammatory agent

b) a cytokine agonist or antagonist

c) an analgesic

d) a steroid

e) an anti-allergic agent

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Claims 3 and 4 are each generic to a plurality of disclosed patentably distinct species listed in the specification. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if

the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600